

EXHIBIT B

Bernasconi, Andrew C.

From: Robinson, Frederick
Sent: Thursday, December 13, 2018 8:56 AM
To: Reynolds, Lesley C.; Chambers, Caitlin A.
Subject: FW: FDA Notification of FOI Request Declined

See below.

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From: FDA_FOI@fda.gov <FDA_FOI@fda.gov>
Date: Thursday, Dec 13, 2018, 8:50 AM
To: Robinson, Frederick <FRobinson@reedsmith.com>
Subject: FDA Notification of FOI Request Declined

Note: Do NOT reply directly to this E-mail

Re: Confirmation # FDA1849163

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

Documents concerning (1) an interview of Steven L. Higgins, M.D., on April 13, 2010 at Scripps Memorial Hospital in La Jolla, California at or about 10:20 AM, that was conducted by Scott K. Zika, FDA Consumer Safety Office and Robert S. Sweeton, FDA Consumer Safety Office (hereafter, the "2010 Investigation"); (2) information provided by Dr. Higgins and others to FDA in the course of the 2010 Investigation and/or any additional investigation concerning purported defects, recalls of the Cognis and Teligen products, as well as their compliance with FDA rules and requirements; (3) FDA's final conclusions and determinations concerning the adequacy of information submitted to FDA by Boston Scientific in connection with Boston Scientific's U.S. launch of its Cognis and Teligen products, including the extent of FDA's knowledge about purported defects of those products that were discovered during and after the European launch of those products; and (4) FDA's final conclusions and determinations concerning the adequacy of Boston Scientific's 2009 recall of the Cognis and Teligen products. PLEASE SEE ATTACHED DOCUMENT FOR MORE SPECIFIC CATEGORIES OF DOCUMENTS REQUESTED.

The request has been declined for following reason:

PLEASE RESUBMIT YOUR REQUEST TO INCLUDE A SIGNED RELEASE FROM THE CLIENT IDENTIFIED IN THE REQUEST. THANK YOU.

FOIA staff may contact you via telephone or email.